

REMARKS

Claims 1 and 4-33 are presented for the Examiner's review and consideration. In this response, claims 1, 4-5, 15 and 26 have been amended; claims 2-3 have been cancelled; and claims 32-33 are new. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Rejections under 35 U.S.C. §102

Waugh

Claims 1-7 were rejected under 35 U.S.C. §102(b) as being anticipated by Waugh et al. (US Pat. 3,869,731) ("Waugh"). Initially, as noted above, claims 2-3 have been cancelled, rendering the rejection as to these claims moot. For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Waugh discloses a two part knee prosthesis which may be substituted for the malfunctioning or diseased human knee... (Col. 2, lns. 16-18). The knee is draped free and the distal portion of the table may be dropped so that the knee hangs at 90° of flexion if desired. (Col. 4, lns. 48-50). A femoral saw guide is now placed in position on the condyles, the reference line on the top edge of the saw guide indicating the location of the anterior edge of the prosthesis, if emplaced without methyl methacrylate. (Col. 5, lns. 21-24). If utilization of methyl-methacrylate is desired, the fin slots are enlarged and undermined with the air saw to accommodate fins and cement. (Col. 5, lns. 28-31).

As such, Waugh discloses a knee replacement, wherein a cutting guide is used to cut condyles while the knee is optionally at 90° of flexion. Cuts are optionally enlarged and undermined to accommodate fins and cement.

Thus, Waugh does not show initiating a cut in the bone while guiding the cutting tool along a guide surface of the guide member to form a cut surface and completing the cut in the bone while guiding the cutting tool along the cut surface. Column 5, lines 21-26 are cited in the rejection as showing completing the cut in the bone while guiding the cutting tool along the cut surface, but Applicant respectfully submits that this does not appear to be reflected in the cited text of Waugh.

Waugh further does not show completing a skim cut, while guiding the cutting tool along the cut surface. Additionally, Waugh does not show the width of the completed cut being at least as long as the distance between the first and second condyles.

In contrast, the present invention discloses a method and apparatus for use in performing any desired type of surgery on a joint in a patient's body. (¶[0009]). The joint may advantageously be a knee joint. (Id). However, the method and apparatus may be used in association with surgery on other joints in a patient's body. (Id).

It is contemplated that the down sized instrumentation may have cutting tool guide surfaces of reduced length. (¶[0014]). The length of the cutting tool guide surfaces may be less than the length of a cut to be made on a bone. (Id). A cut on a bone in the patient may be completed using previously cut surfaces as a guide for the cutting tool. (Id).

During the anterior cut, a blade 170 of a saw 172 is utilized to make a cut across anterior portions of the lateral and medial condyles. (¶[0137]). The saw blade 170 is moved along guide surface 178 (FIGS. 11 and 12) on the anterior resection guide 138. (Id).

During completion of the anterior femur (skim) cut, previously cut surfaces on the end portion 124 of the femur 126 are used to guide the saw blade 170 (FIG. 13). (¶[0142]). Thus, an initial portion of the anterior skim cut is made on the distal end portion 124 of the femur 126 while the saw blade 170 is moved along one or more guide surfaces on the anterior resection guide 138. (Id). After the anterior resection guide 138 has been disconnected from the femoral alignment guide 134, the saw blade 170 is positioned in engagement with the cut surfaces on the distal end portion 124 of the femur 126. (Id). This is accomplished by inserting the saw blade 170 into a slot or saw kerf formed in the distal end portion 124 of the femur during the initial portion of the anterior skim cut. (Id).

As such, the present invention discloses a reduced size cutting guide that is positioned against the bone, initiating the cut along the guide surface, and completing a skim cut while guiding the tool along the cut surface. The width of the completed cut is wider than the distance between the first and second condyles.

Claim 1 recites, *inter alia*, a method of performing surgery on a patient's knee, the method comprising: suspending a distal portion of a patient's leg from the knee; cutting a bone of the

knee with a cutting tool while the distal portion of the patient's leg is suspended from the knee; positioning a guide member against the bone, and cutting the bone includes initiating a cut in the bone while guiding the cutting tool along a guide surface of the guide member to form a cut surface, then completing a skim cut, while guiding the cutting tool along the cut surface; and positioning a total knee replacement component against the cut bone of the knee, wherein cutting the bone includes cutting first and second condyles of the bone, and wherein the length of the completed cut is at least as long as the distance between the first and second condyles of the bone.

Accordingly, Applicant respectfully submits that claim 1 is patentable over Waugh. As claims 4-7 depend from claim 1, these dependent claims necessarily include all the elements of their base claim. Accordingly, applicant respectfully submits that the dependent claims are allowable over Waugh for the same reasons.

Techiera

Claims 15-18 and 21-27 were rejected under 35 U.S.C. §102(e) as being anticipated by Techiera (US Pat. 6,106,529) ("Techiera"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Techiera discloses a tool which sets a resection or alignment feature to position a prosthetic joint component. (Col. 2, lns. 54-56). The tool is used at the distal femoral resected surface, and includes one or more assemblies coupled to a main body for alignment with the epicondylar axis, and which set the orientation of the main body. (Id). The main body positions a cutter, e.g., includes a drill guide or saw blade guide. (Id).

Before making a determinative cut or drill hole, the body may be shifted laterally to optimize the component position for load bearing or patellar tracking. (Col. 3, lns. 8-10). ...the tool locator body 60 may be adapted in other embodiment as a saw cut guide rather than a drill guide, or both, in order to position a slot or other cut feature which similarly functions to orient and position one or more cutting blocks. (Col. 5, lns. 45-49).

As such, Techiera discloses a resection alignment tool, including a drill guide or saw blade guide. The tool may be adapted as a saw cut guide to position a slot or other cut feature.

Thus, Techiera does not show how the tool may actually be used to make a cut. Thus, Techiera does not disclose initiating a cut in the bone while guiding the cutting tool along the guide surface to form a cut surface. Techiera further does not disclose continuing the cut in the bone while guiding the cutting tool along the cut surface. In addition, Techiera does not disclose positioning a first portion of a total knee replacement against a cut bone, and subsequently positioning a second portion of the total knee replacement against the cut bone, and connecting the portions after both have been positioned against the cut bone. There is further no disclosure in Techiera for angularly disposing the cutting tool along the guide surface in order to cut a section of the bone wider than the width of the guide.

In contrast, in addition to the disclosures recited above, the present invention further discloses, with reference to Fig's. 13-15, 19-23, and 53-54, that the incision 114 must be large enough to enable the femoral alignment guide 134 and the anterior resection guide 138 to pass through the incision. (¶[0129]). ... if the incision 114 was offset laterally of the patella 120, the femoral alignment guide 134 and the anterior resection guide 138 would extend laterally from the center portion of the femur 126. (¶[0130]).

To enable the size of the incision 114 to be minimized, the instrumentation is moved laterally of the incision so that a portion of the instrumentation moves between the knee capsule and the end portion 124 of the femur 126. (¶[0133]). This results in a portion of the instrumentation being exposed at the incision 114 and a laterally extending portion of the instrumentation being concealed by body tissue. (Id).

When anterior portions of the lateral and medial condyles 148 and 150 (FIGS. 10, 11 and 12) on the distal end portion 124 of the femur 126 are to be cut with the saw 172, the blade 170 is pivoted sideways (FIG. 13) so that the cutting end of the blade has an arcuate component of movement. (¶[0139]). The cutting end of the blade 170 will move along a straight path during part of the movement of the blade along the guide surface 178. (Id). However, when the blade 170 reaches the ends of the guide surface 178, the saw 172 is pivoted to pivot the blade and move the cutting end of the blade along a path having an arcuate configuration. (Id).

In order to enable surgery on a knee portion 76 of a patient's leg 70 to be conducted through an incision 114 of relatively small size, the implant may advantageously be formed in two or more portions (FIG. 40). ([0311]). The portions of the implant are sequentially moved through the incision 114 into engagement with the distal end portion 124 of the femur 126 and/or the proximal end portion 212 of the tibia 214. (Id). After the plurality of portions of the implant have been moved through the incision 114 and positioned in engagement with the femur 126 and/or tibia 214, the portions of the implant are interconnected to form a unitary implant. ([0312]).

As such, the present invention discloses inserting a total knee replacement where a first and subsequently a second portion of the implant is positioned on the bone, then connected once both portions have been positioned, thus enabling an implant that is larger than the incision.

To further aid in reducing the size of the incision, the cutting tool is angularly disposed along the guide surface, so that a section of the bone wider than the width of the guide may be cut. Angularly displacing the cutting tool thus decreases the size of the cut to be completed along the cut surface. Further, the step facilitates mounting a reduced size cutting guide laterally to a line defining the longitudinal axis of the bone to be cut, cooperative with a laterally formed incision.

Claim 15 recites, *inter alia*, method of performing surgery on a patient's joint, the method comprising: positioning a guide member against a bone of the joint, the guide member having a guide surface; positioning a cutting tool in association with the guide surface of the guide member; initiating a cut in the bone while guiding the cutting tool along the guide surface to form a cut surface; continuing the cut in the bone while guiding the cutting tool along the cut surface; positioning a first portion of a total knee replacement against the cut bone, and subsequently positioning a second portion of the total knee replacement against the cut bone; and connecting the first and second portions of the total knee replacement component after both portions have been positioned against the cut bone.

Claim 26 recites, *inter alia*, a method of performing a total knee arthroplasty surgery on a leg of a patient, the method comprising: positioning a guide member against a bone of a knee joint in the leg of the patient, the guide member having opposite ends with a transverse dimension which is less than a distance between medial and lateral epicondyles of an end portion of the bone; positioning a cutting tool in association with a guide surface of the guide member; initiating a cut in the bone while guiding the cutting tool along the guide surface to form a cut surface; angularly disposing the cutting tool along the guide surface in order to cut a section of the bone wider than the width of the guide; and continuing the cut in the bone while guiding the cutting tool along the cut surface, wherein both medial and lateral condyles of the end portion of the bone are cut by the cutting tool.

Accordingly, Applicant respectfully submits that claims 15 and 26 are patentable over Techiera. As claims 16-18, and 21-25 depend from claim 15, and claim 27 depends from claim 26, these dependent claims necessarily include all the elements of their base claim. Accordingly, applicant respectfully submits that the dependent claims are allowable over Techiera for the same reasons.

In light of the foregoing, Applicant request reconsideration and withdrawal of the section 102 rejections.

Rejections under 35 U.S.C. §103

Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Waugh in view of Sherwin (US Pat. 3,750,652) (“Sherwin”). Claims 9-10, and 13-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Waugh in view of Shapiro (US Pat. 4,565,192) (“Shapiro”). Claims 9-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Waugh in view of Waddell (US Pat. 6,174,314) (“Waddell”). Claim 19 was rejected under 35 U.S.C. §103(a) as being unpatentable over Techiera in view of Waugh. Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Techiera in view of Sherwin. Claims 28-31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Techiera.

Initially, as noted above, claims 2-3 have been cancelled, rendering the rejection as to these claims moot. For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

As described above, Applicant submits that claim 1 is patentable over Waugh. Applicant further submits that Sherwin, Shapiro, Waddell, and Techiera do not correct the deficiencies of Waugh with respect to claim 1. As claims 8-14 depend from claim 1, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Waugh in view of the cited references for the same reasons.

As further described above, Applicant submits that claim 15 is patentable over Techiera. Applicant submits that Waugh and Sherwin do not cure the deficiencies of Techiera with respect to claim 15. As claims 19-20 depend from claim 15, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Techiera in view of the cited references for the same reasons.

Additionally, as described above, Applicant submits that claim 26 is patentable over Techiera. As claims 28-31 depend from claim 26, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over Techiera.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejections.

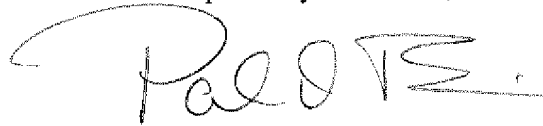
Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested.

If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No Fee is believed to be due. However, please charge any required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A04-012-1A).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul D. Bianco', with a large, sweeping initial 'P'.

Paul D. Bianco, Reg. # 43,500

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